

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA; STATES OF
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, VERMONT, AND WASHINGTON;
THE COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA; AND
THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH &
DEVELOPMENT, LLC, JOHNSON &
JOHNSON, and BTG INTERNATIONAL
LIMITED,

Defendants.

PLAINTIFF-RELATOR ZACHARY SILBERSHER'S INITIAL DISCLOSURES

**LITE DEPALMA GREENBERG
& AFANADOR, LLC**

Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

Attorneys for Plaintiff-Relator Zachary Silbersher

[Additional Counsel on Signature Page]

Pursuant to Fed. R. Civ. P. 26(a)(1), Plaintiff-Relator Zachary Silbersher (“Plaintiff” or “Relator”) makes the following initial disclosures to Defendants.

PRELIMINARY STATEMENT

Plaintiff makes these initial disclosures based on information reasonably available to him at this time. Plaintiff’s initial disclosures represent a good faith effort to identify information currently available to him that he reasonably believes is discoverable and supportive of his claims as required by the Federal Rules of Civil Procedure. By making these disclosures, Plaintiff does not represent that he is identifying or producing every witness on which he may ultimately rely to prove his claims. In addition, it is possible that some individuals listed here may not, in fact, possess significant information regarding the issues involved in this litigation, or may only have knowledge that is duplicative of knowledge possessed by others. Plaintiff reserves the right to further amend, supplement or correct these disclosures upon continuing investigation and discovery in accordance with Fed. R. Civ. P. 26(e). Further, Plaintiff will submit a witness list at a time to be set by the Court.

Plaintiff makes these initial disclosures subject to and without waiving his right to protect from disclosure any attorney-client privileged documents or work product of his attorneys and other representatives, including but not limited to, their mental impressions, conclusions, opinions, or legal theories. Plaintiff further make these initial disclosures without waiving any right or opportunity to assert a defense or otherwise present, at any time in this lawsuit, information, including information contained in any and all documents, addressing facts and issues other than those identified here.

Plaintiff’s initial disclosures are made without waiving in any way: (i) the right to object on the grounds of competency, privilege, relevancy and materiality, undue burden, hearsay, or any other proper ground, to the use of any such information, for any purpose, in whole or in part, in any subsequent proceeding in this action or any other action; and (ii) the right to object on any grounds, at any time, to any other discovery request or proceeding involving or relating to the subject matter of these disclosures.

These disclosures do not include the names of any potential experts retained or consulted by the Plaintiffs. Plaintiffs will produce information relating to experts as may be appropriate under Rule 26(a)(2) at the times provided by that rule or order of the Court.

Finally, Plaintiff may further affirm, clarify, modify, or otherwise develop his claims in this lawsuit. Therefore, Plaintiff reserves the right, at any time, to identify additional individuals, if any, that may have discoverable information pertinent to any such claims.

I. Rule 26(a)(1)(A)(i): Individuals Likely to Have Discoverable Information that Plaintiff May Use to Support His Claims or Defenses

Subject to the above reservations and objections, Plaintiff believes that the persons or entities listed below are likely to have discoverable information that Plaintiff may use to support his claims. Plaintiff makes no representations as to the extent of knowledge of these individuals. This is a preliminary list based upon the information that is currently known to Plaintiff. Plaintiff retains the right to modify or supplement this list as the circumstances may warrant and as otherwise permitted by the Court. All disclosures are made without waiver of any applicable privileges or other objections to the use or production of information or knowledge held by these people or entities.

Plaintiff also identifies as individuals with discoverable information any and all witnesses needed to authenticate documents or any other evidence at issue in the litigation.

In addition, the following categories of persons likely possess discoverable information:

(1) Plaintiff, who can be contacted through his undersigned attorneys. Plaintiff has knowledge of all the allegations in the Second Amended Complaint (the “Complaint”) and Plaintiff’s status as an original source of the material allegations of fraud alleged in the Complaint.

(2) Defendants, including but not limited to their officers, directors, employees, and agents whose identities are not currently known by Plaintiff, and including Defendants’ subsidiaries, divisions, or predecessors. The identity of Defendants’ officers, directors, employees, and agents with knowledge will be determined through discovery. Plaintiff believes such individuals worked for Defendants at least for some period of time during the relevant time

period. Plaintiff believes they are likely to have discoverable information that Plaintiff may use to support his claims on one or more of the following subjects:

(a) Defendants' decision to apply for and prosecute U.S. Patent No. 8,822,438 ("the '438 Patent").

(b) Defendants' decision to mislead the U.S. Patent Office about the purported validity of the claims of the '438 Patent (and the facts underlying the misrepresentations or the true state of facts that were the subject of the misrepresentations), including, without limitation, misrepresenting the obviousness of the claimed invention claimed in the '438 Patent; secondary considerations purportedly surmounting the obviousness of the claimed invention; and the nature and source of the supposed commercial success of the invention claimed;

(c) Defendants' decision to assert the '438 Patent against potential generic entrants, including in sham litigation;

(d) Defendants' plans to protect Zytiga against generic competition;

(e) Defendants' claims for payment or reimbursement for Zytiga from any government agency or government-funded health programs;

(f) the submission and approval of any Abbreviated New Drug Application ("ANDA") for which Zytiga is the reference-listed drug, including any supplements or communications related thereto;

(g) sales, marketing, pricing, manufacturing, production, and production capacity of Zytiga;

(h) Defendants' revenue and profit margins for Zytiga sales;

(i) Defendants' costs related to producing Zytiga;

(j) the nature, scope and effect of Defendants' fraudulent scheme as alleged in the Complaint;

(k) the impact of Defendants' fraudulent scheme on government funded health programs including, without limitation, overcharges paid or reimbursed by any government or government agency relating to Zytiga, and any payments or reimbursements for Zytiga that would have been substituted for a lower-cost generic but for Defendants' wrongful exclusion of

generic competitors through Defendants' fraudulent scheme; and the damages sustained by the federal Government and the Plaintiff States; and

(l) The concealment of Defendants' misconduct.

The foregoing list of subject matter areas is not exhaustive and is offered without prejudice to Plaintiff's right to obtain information from Defendants that is reasonably calculated to lead to the discovery of admissible evidence.

At this time, Plaintiff has ascertained that the Defendants' officers and employees and patent inventors possessing discoverable information include, but are not limited to, at least the following individuals:

Name	Title, Position or Company	Subject Matter	Address
Alan H. Auerbach	Inventor of the '438 Patent	(a)-(d), (f), (g), (j), and (l)	Upon information and belief, Auerbach may be reached at his current company, Puma Biotechnology, 10880 Wilshire Blvd., Suite 2150, Los Angeles, CA 90024 (tel.) 424-248-6500
Arie S. Belldegrun	Inventor of the '438 Patent	(a)-(d), (f), (g), (j), and (l)	Upon information and belief, Belldegrun may be reached at UCLA Medical Center, 757 Westwood Plaza. Los Angeles, California 90095
Andrea Jo Kamage	In-house counsel at defendant Johnson & Johnson	(a)-(d), (f), (g), (j), and (l)	Upon information and belief, Kamage can be reached at 1 Johnson and Johnson Plaza, New Brunswick, NJ 08901

(3) Employees and agents of nonparty generic drug manufacturers. The current and former employees and agents (to be identified through discovery) of nonparty generic manufacturers that filed or considered filing ANDAs for generic Zytiga may possess relevant

information concerning (1) the submission and approval of any ANDA for which Zytiga is the reference-listed drug, including any supplements or communications related thereto, (2) bioequivalence guidance regarding Zytiga, (3) citizen petitions concerning Zytiga or generic Zytiga, including any supplements, responses, or communications related thereto, (4) litigation and Patent Trial and Appellate Board proceedings related to any patents allegedly covering Zytiga, (5) patents prosecuted and issued in connection with Zytiga, and (6) Defendants' efforts to exclude generic competitors from the market by asserting patents they knew were invalid in sham litigations. These entities include but are not limited to the entities listed in paragraph 94 of the Second Amended Complaint (Dkt. 63).

(4) Other non-parties. The identity of any third parties with knowledge will be determined through discovery. This information may include evidence regarding the subjects listed in (a) through (l), *supra*, and in Paragraph (3), *supra*.

(5) Employees and Agents of Government Entities. Current and former employees and agents of the U.S. Food and Drug Administration (to be identified through discovery) may possess relevant information concerning: (a) the submission and approval of Defendants' New Drug Application for Zytiga, including any supplements or communications related thereto, (b) the submission and approval of any ANDA for which Zytiga is the reference-listed drug, including any supplements or communications related thereto, (c) bioequivalence guidance regarding Zytiga, (d) citizen petitions concerning Zytiga or generic Zytiga, including any supplements, responses, or communications related thereto, and (e) patents identified in the FDA's records as covering Zytiga.

Current and former employees and agents of the U.S. Patent and Trademark Office (to be identified through discovery) may possess relevant information concerning the prosecution of patent applications and/or issuance of the patents pertaining to or covering Zytiga.

Current and former employees of government agencies (to be identified through discovery) that have paid or reimbursed for prescriptions of Zytiga or otherwise negotiated the prices for the drugs.

Additional information concerning Plaintiff may be provided in amended disclosures after further investigation and discovery.

II. Rule 26(a)(1)(A)(ii): Documents and Information That Plaintiff May Use to Support His Claims or Defenses

Subject to the above reservations and objections, including Plaintiff's right to modify, supplement or clarify his response, Plaintiff, through his counsel, represents that Plaintiff has in his possession, custody or control the following categories of documents, electronically stored information and tangible things: files, documents and data concerning the obviousness of the claimed invention in the '438 Patent and the misleading nature of the secondary considerations submitted by Defendants purportedly surmounting the obviousness of the claimed invention; certain unsealed documents in Patent Trial and Appellate Board and district court proceedings invalidating the '438 Patent; certain available patent file wrapper documents for the '438 Patent; and certain unsealed documents in sham litigation that Defendants commenced against generic competitors to exclude them from the market.

These documents have been and will be made available for inspection or copying in response to any Rule 34 requests for the production of documents served upon Plaintiff by Defendants according to a schedule to be agreed to by the parties, and, where appropriate, subject to a discovery confidentiality order.

Additional documents that Plaintiff may use to support their claims and defenses are likely in the possession, custody, or control of Defendants and third parties or are publicly available, such as patent litigations filings and orders and FDA documents.

III. Rule 26(a)(1)(A)(iii): Computation of Plaintiff's Damages

At this time, Plaintiff cannot state the exact amount of damages the federal Government and Plaintiff States have suffered as a result of Defendants' misconduct. Discovery has not yet commenced. Prior to Plaintiff's receipt and analysis of full discovery from Defendants, an estimation of Plaintiff's damages would be premature. Plaintiff further states that expert testimony may be required to calculate the full compensation and restitution to which Plaintiff

and each of the proposed class members are entitled. Subject to the foregoing, Plaintiff seeks compensation and statutory penalties, as follows:

Plaintiff seeks damages on behalf of the federal government and the Plaintiff States for overcharges paid for Zytiga (or the full amount paid for Zytiga that would have otherwise been paid to generic competitors) from at least December 2016 through end of 2019. Medicare Part D payments during the relevant time period was approximately \$3.2 billion, and Medicaid payments for Zytiga totaled approximately \$180 million. These amounts do not include Zytiga purchases by other government-funded health programs, such as the Veterans Health Administration.

Plaintiff believes the government and the Plaintiff States may recover the full amount of any Zytiga invoices, either because a lower cost generic would have been substituted for Zytiga but for Defendants' fraudulent scheme, or under a fraudulent inducement theory of liability. With trebling under 31 U.S.C. § 3729(a)(1), the government's recovery without statutory penalties would exceed \$10 billion, excluding damages relating to any direct purchases from the Veterans Health Administration, the Department of Defense's TRICARE, or other government-funded health programs.

But even if the government is entitled to only recover the overcharge amount, if generics had been able to enter the market, the price of abiraterone acetate would have dropped by 85% to 95%. The amount of this overcharge would be at least \$2.9 billion, just for Medicare Part D and Medicaid.

The FCA also authorizes a civil penalty of not less than \$11,665, or more than \$23,331, for each violation of the False Claims Act. Medicare Part D (315,500 claims) and Medicaid (20,000 claims) paid 335,500 total claims for Zytiga during the minimum relevant damages period. Accordingly, the minimum civil penalty would be approximately \$3.9 billion, and the maximum civil penalty would be approximately \$7.4 billion, just for these claims to Medicaid and Medicare Part D alone. Adding the treble damages to the civil penalties, Plaintiff seeks, at a minimum, damages of approximately between \$14 billion and \$17.4 billion (excluding damages from other Medicare claims and direct purchases from other government programs), plus

reasonable expenses, attorneys' fees, and costs, as authorized under 31 U.S.C. 3730(d)(2). This amount excludes any applicable additional penalties under the laws of the Plaintiff States.

Plaintiff will supplement this disclosure as additional facts are ascertained and discovery progresses.

IV. Rule 26(a)(1)(A)(iv): Insurance Policies

None.

Dated: July 16, 2021

**LITE DEPALMA GREENBERG
& AFANADOR, LLC**

/s/ Bruce D. Greenberg

Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
bgreenberg@litedepalma.com

HERRERA KENNEDY LLP

Nicomedes Sy Herrera (*pro hac vice*)
Laura E. Seidl (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com
LSeidl@HerreraKennedy.com

GOLDSTEIN & RUSSELL, P.C.

Tejinder Singh (*pro hac vice*)
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636
TSingh@goldsteinrussell.com

***Attorneys for Plaintiff-Relator
Zachary Silbersher***

EXHIBIT B

Jeffrey J. Greenbaum
Gregory E. Reid
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102

Gordon D. Todd (*pro hac vice*)
Robert D. Keeling (*pro hac vice*)
Kimberly Leaman (*pro hac vice*)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005

*Attorneys for Defendants Janssen
Biotech, Inc., Janssen Oncology, Inc.,
Janssen Research & Development, LLC,
and Johnson & Johnson*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA, ET AL., ex
rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH &
DEVELOPMENT, LLC, and JOHNSON &
JOHNSON,

Defendants.

Civil Action No. 19-12107 (KM) (ESK)

**DEFENDANTS JANSSEN
BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN
RESEARCH & DEVELOPMENT,
LLC, AND JOHNSON &
JOHNSON'S REVISED FIRST
REQUESTS FOR PRODUCTION OF
DOCUMENTS TO RELATOR
ZACHARY SILBERSHER**

Pursuant to Federal Rules of Civil Procedure 26 and 34, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson, request that Relator Zachary Silbersher produce each of the documents and information requested below to Sidley Austin LLP, 1501 K St. N.W., Washington, D.C. 20005 (Attention: Kimberly Leaman) within thirty (30) days of service of this request (or in accordance with the Court's February 25, 2022 Order, *see* Dkt. 193).

DEFINITIONS

The following definitions apply to each of the Requests below:

1. The singular shall be construed to include the plural, and vice versa, to make the discovery request inclusive rather than exclusive.
2. The words "AND" and "OR," even when used without the other, shall be construed conjunctively or disjunctively as is necessary to make the discovery request inclusive rather than exclusive.
3. The words "ANY," "ALL," and "EACH," even when used without another, shall be construed disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.
4. The terms "DOCUMENT" and "DOCUMENTS" shall include those definitions contained in Fed. R. Civ. P. 34(a)(1)(A), Fed. R. Evid. 101(b)(4), and Fed. R. Evid. 1001. These requests do not seek or require production of multiple, identical copies of a document (i.e., identical versions of a document that do not contain different notations, marks, alterations, data, comments, or other changes). "DOCUMENT" includes both tangible materials and electronically stored information ("ESI").
5. The term "RELATING TO" shall be read broadly and encompasses relating to, concerning, referring to, reflecting on, arising out of, supporting, negating, disclosing, memorializing, analyzing, reporting, communicating, showing, discussing, underlying, and constituting.
6. The term "DEFENDANTS" means Janssen Biotech, Inc., Janssen Oncology, Inc.,

Janssen Research & Development, LLC, and Johnson & Johnson.

7. The term “’438 PATENT” refers to United States Patent No. 8,822,438, titled “Methods and Compositions for Treating Cancer,” including any application that claims priority to, or from which priority is claimed by, any of the applications that issued as the ’438 patent.

8. The terms “CLAIM” or “CLAIMS” means any request or demand, whether under a contract or otherwise, for payment or reimbursement submitted to the Federal and/or State Government.

9. The term “USPTO” refers to the United States Patent and Trademark Office.

10. The term “FEDERAL GOVERNMENT” refers to any agency, branch, unit, or department of the federal government, including but not limited to the U.S. Food and Drug Administration, the USPTO, the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs, the U.S. Department of Justice, and/or any person or entity working on its behalf.

11. The term “STATE GOVERNMENT” refers to any agency, branch, unit, or program of a state government (including the District of Columbia) and/or any person or entity working on its behalf.

12. The term “LITIGATION” refers to *Silbersher et al. v. Janssen Biotech, Inc. et al.*, Civil Action No. 19-12107 (D.N.J.).

13. The terms “YOU” or “YOUR” refer to Relator Zachary Silbersher, including attorneys acting on Relator Zachary Silbersher’s behalf and persons employed or retained by Markman Advisors or Kroub, Silbersher & Kolmykov PLLC.

14. The terms “PERSON” and “PERSONS” include any natural person, firm, association, organization, partnership, business, trust, corporation, or public entity.

15. The term “ZYTIGA” means the drug product marketed under New Drug Application No. 202379 that has been approved by the U.S. Food and Drug Administration for manufacture and sale (i.e., abiraterone acetate) and is indicated for use in combination with prednisone.

INSTRUCTIONS

1. Documents must be produced in accordance with the Stipulation and Order Concerning Protocol For Discovery Of Electronically Stored Information and Hardcopy Documents entered into between the Parties, Dkt. 160 (Jul. 19, 2021), or as agreed by the parties or as ordered by the Court in any supplemental ESI protocol.

2. These Requests pertain to all responsive documents in Your possession, custody, or control, including the control of Markman Advisors, Kroub, Silbersher & Kolmykov PLLC, or any attorneys or consultants engaged by You or acting on Your behalf.

3. Documents not otherwise responsive to these Requests shall be produced if such documents are attached to documents that are responsive to these Requests and constitute routing slips, transmittal memoranda, letters, cover sheets, comments, evaluations, or similar materials.

4. The requests below are continuing in nature pursuant to Rule 26(e) of the Federal Rules of Civil Procedure.

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION 1:

All documents relating to Your allegations that Defendants submitted or caused to be submitted false or fraudulent Claims for Zytiga to the Federal and/or State Government.

REQUEST FOR PRODUCTION 2:

All documents relating to Your allegations that Defendants acted with the requisite knowledge or scienter, as set forth in Paragraphs 134 through 138 of the Second Amended Complaint.

REQUEST FOR PRODUCTION 3:

All documents relating to Your allegations, including but not limited to those in Paragraph 142 of the Second Amended Complaint, that Defendants knowingly (a) submitted false records and/or (b) made false statements to the Federal and/or State Government in connection with Claims for Zytiga, including such false records or statements.

REQUEST FOR PRODUCTION 4:

All documents relating to allegations in the Second Amended Complaint that (a) Defendants' representations and/or omissions to the USPTO during the prosecution of the '438 Patent were false, misleading, deceptive, or otherwise fraudulent, including the allegations set forth in Paragraphs 82 through 90 of the Second Amended Complaint; and (b) Defendants had knowledge that the '438 Patent was invalid or unenforceable.

REQUEST FOR PRODUCTION 5:

All documents relating to the commercial success of Zytiga, including but not limited to the reasons for Zytiga's commercial success and/or market share.

REQUEST FOR PRODUCTION 6:

All documents relating to actual or potential (a) competition, (b) market share, (c) relative price and/or cost, and (d) utilization rates between Zytiga, generic equivalents of Zytiga, and/or any pharmaceutical product approved for one or more of the same indications as Zytiga.

REQUEST FOR PRODUCTION 7:

All documents relating to any comparisons between and among Zytiga and any other pharmaceutical product approved for one or more of the same indications as Zytiga, including but not limited to actual, projected, or claimed use, and benefit, harm, improvement, therapeutic equivalence, effectiveness, similarity, or difference between or among those treatments.

REQUEST FOR PRODUCTION 8:

All documents relating to Your allegations in the Second Amended Complaint, including those in Paragraphs 92 through 105 of the Second Amended Complaint, that Defendants fraudulently intended to exclude generic competitors from the market.

REQUEST FOR PRODUCTION 9:

All documents regarding or relating to the effect of a generic product's entry into the market on Zytiga.

REQUEST FOR PRODUCTION 10:

All documents relating to Your allegations that the price of Zytiga was "artificially

inflated.”

REQUEST FOR PRODUCTION 11:

All documents relating to Your allegation that Claims for generic versions of abiraterone acetate would have replaced approximately 90% of Claims for Zytiga submitted to the Federal and/or State Government.

REQUEST FOR PRODUCTION 12:

All documents showing or tending to show whether the Federal and/or State Government considers patent status as part of its contracting, reimbursement, or payment procedures for pharmaceutical drugs.

REQUEST FOR PRODUCTION 13:

All documents relating to (a) the following articles written by You on the MarkmanAdvisors.com Patent Blog: *Will MorphoSys win the Darzalex patent case against Janssen and Genmab?* and *Is J&J's Remicade® part of the “rigged” system claimed by FDA's Gottlieb? Pfizer's Inflectra® antitrust suit has the answer*; and (b) any articles, posts, or commentary You have authored or co-authored, regardless of where posted or published, relating to whether the Federal Government does or should consider patent validity when approving an application for the sale and marketing of a pharmaceutical drug and/or regulate the use of patents in connection with the sale and marketing of a pharmaceutical drug.

REQUEST FOR PRODUCTION 14:

All documents regarding or relating to any research, investigation, or analysis addressing or evaluating (a) the effect that obtaining multiple patents on a brand name pharmaceutical product has on that product's price or (b) theories of potential liability that could arise from alleged fraudulent or inequitable conduct in a patent prosecution.

REQUEST FOR PRODUCTION 15:

All documents and communications relating to any investigation, including but not limited to the initiation of any such investigation, that You or anyone on Your behalf conducted regarding Defendants' application for, or prosecution or enforcement of, the '438 Patent; the

granting of the '438 Patent or the listing of the '438 Patent in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the "Orange Book"; any Claims for payment or reimbursement for Zytiga; and/or any other facts related to the subject matter of this Litigation.

REQUEST FOR PRODUCTION 16:

All documents relating to Zytiga, the '438 Patent, Defendants, or the subject matter of this Litigation.

REQUEST FOR PRODUCTION 17:

All documents and communications exchanged between You and any person, including but not limited to the Federal and/or State Government, relating to Zytiga, the '438 Patent, Defendants, or this Litigation.

REQUEST FOR PRODUCTION 18:

All documents relating to Your submissions to and/or meetings with the Federal and/or State Government, including but not limited to the submissions to or meetings with the Federal Government and any other State Government on November 2, 2018 and June 5, 2019, as set forth in Paragraph 17 of the Second Amended Complaint, or on any other date.

REQUEST FOR PRODUCTION 19:

All documents used, referenced, or relied upon in drafting or otherwise underlying any iteration of Your Complaint in this Litigation.

REQUEST FOR PRODUCTION 20:

All documents, including but not limited to research summaries, analyses, memoranda, investigation material, or reports, that You contend make You an "original source" within the meaning of the False Claims Act as set forth in Paragraph 17 of the Second Amended Complaint.

REQUEST FOR PRODUCTION 21:

All documents that You provided to the Federal and/or State Government relating to Zytiga, the '438 Patent, or this Litigation and which You claim the Federal and/or State Government did not previously have or could not have acquired through publicly available

resources.

REQUEST FOR PRODUCTION 22:

All documents relating to the pricing and listing of Zytiga on the Federal Supply Schedule.

REQUEST FOR PRODUCTION 23:

All documents relating to the listing of the '438 Patent in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the "Orange Book."

REQUEST FOR PRODUCTION 24:

Documents sufficient to show each client that You and/or Markman Advisors have represented in a consultant role since 2015.

REQUEST FOR PRODUCTION 25:

Documents sufficient to show each client that You and/or Kroub, Silbersher & Kolmykov PLLC have represented as legal counsel since 2015.

REQUEST FOR PRODUCTION 26:

All documents provided to any of Your or Markman Advisors' consulting clients or potential consulting clients relating to (a) fraud or inequitable conduct in a patent prosecution; (b) the effect and/or propriety of obtaining multiple patents on a single brand name drug; (c) the use or application of a "commercial success" argument to procure a patent; and/or (d) theories of liability for conduct before the USPTO.

REQUEST FOR PRODUCTION 27:

All communications with Flat Line Capital LLC, or any person acting on Flat Line Capital LLC's behalf, relating to the claims and allegations in *United States ex rel. Silbersher v. Valeant Pharm. Int'l Inc., et al.*, Civil Case No. 3:18-cv-01496-JD (N.D. Cal.), including the origin of information resulting in those claims and allegations, and any documents and communications with current and/or former clients relating to the use of information for litigation pursuant to the False Claims Act, 31 U.S.C. §§ 3729 – 3733, or Federal antitrust laws,

and documents concerning those communications.

REQUEST FOR PRODUCTION 28:

Documents sufficient to show matters before Federal courts and/or the USPTO, including the Patent Trial and Appeal Board, in which You have appeared on behalf of, or acted as a consultant for, (a) parties asserting a patent infringement claim and/or (b) patent owners defending an *inter partes* review challenge.

REQUEST FOR PRODUCTION 29:

All documents relating to any case, other than this Litigation, that You have either filed as a Relator, plan to file as a Relator, appear as legal counsel, or plan to appear as legal counsel, that includes an allegation that a false Claim has been submitted to the Federal and/or State Government.

REQUEST FOR PRODUCTION 30:

All documents relating to any funding you have solicited, considered, and/or received for this Litigation.

REQUEST FOR PRODUCTION 31:

Documents relating to Your alleged damages in this Litigation, including but not limited to calculation of damages and penalties sought by Your Litigation.

REQUEST FOR PRODUCTION 32:

All documents identified in Your Rule 26 Initial Disclosures served on Defendants and any supplements to those Initial Disclosures You may serve in the future.

REQUEST FOR PRODUCTION 33:

All documents You have received, or will receive, from non-parties in connection with this Litigation, including all documents You have received or will receive pursuant to any third-party subpoena duces tecum.

Dated: March 25, 2022

By: /s/ Jeffrey J. Greenbaum
JEFFREY J. GREENBAUM
jgreenbaum@sillscummis.com
GREGORY E. REID
greid@sillscummis.com
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
Phone: (973) 643-7000

GORDON D. TODD (*pro hac vice*)
gtodd@sidley.com
ROBERT D. KEELING (*pro hac vice*)
rkeeling@sidley.com
KIMBERLY LEAMAN (*pro hac vice*)
kimberly.leaman@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005

*Attorneys for Defendants Janssen Biotech, Inc.,
Janssen Oncology, Inc., Janssen Research &
Development, LLC, and Johnson & Johnson*

EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA; STATES OF
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, VERMONT, AND WASHINGTON;
THE COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA; AND
THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH &
DEVELOPMENT, LLC, JOHNSON &
JOHNSON, and BTG INTERNATIONAL
LIMITED,

Defendants.

Civil Action No.: 19-12107 (KM)(JBC)

**PLAINTIFF-RELATOR RESPONSES TO DEFENDANTS' FIRST SET OF
REQUESTS FOR PRODUCTION OF DOCUMENTS**

**LITE DEPALMA GREENBERG
& AFANADOR, LLC**

Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

Attorneys for Plaintiff-Relator Zachary Silbersher
[Additional Counsel on Signature Page]

GENERAL OBJECTIONS

Pursuant to Fed. R. Civ. P. 26 and 36, Plaintiff-Relator Zachary Silbersher hereby object to defendants' First Requests for Production of Documents (collectively, "Requests") as follows:

Each of Plaintiff's responses, in addition to any specifically stated objections, is subject to and incorporates the following General Objections. The assertion of the same, similar, or additional objections, or a partial response to an individual Request does not waive any of Plaintiff's General Objections.

Plaintiff objects to these Requests to the extent that they are overbroad and unduly burdensome and to the extent that they seek to impose burdens or obligations inconsistent with, or in excess of, those imposed by the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of New Jersey, or any other applicable rules and statutes.

Plaintiff objects to these Requests to the extent that they seek information that is neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence.

Plaintiff objects to these Requests to the extent that they seek information protected from disclosure by the attorney-client privilege, the attorney work product doctrine, or any other applicable privilege, protection, or immunity. No information subject to such privilege, protection, or immunity will be provided.

The inadvertent disclosure by Plaintiff of information protected by the attorney-client privilege, the attorney work product doctrine, or any other applicable privilege, protection, or immunity, shall not constitute a waiver by Plaintiff of such protection.

In response to these Requests, Plaintiff does not concede that any of the responses or information contained herein is relevant or admissible. Plaintiff reserves the right to object, on the grounds of competency, privilege, relevance, materiality, or otherwise, to the use of this information for any purpose, in whole or in part, in this action or in any other action.

Plaintiff objects to these Requests to the extent that they call for legal conclusions or otherwise attempt to re-cast legal issues as factual matters.

Plaintiff objects to any Request that employs imprecise specifications of the information sought as vague and ambiguous.

Unless otherwise stated, Plaintiff will not provide any information encompassed by the foregoing objections.

Plaintiff objects to the definition of “YOU” or “YOUR” as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence to the extent that definition encompasses Persons other than Plaintiff-Relator Zachary Silbersher. In the responses below, we limit “YOU” and “YOUR” to Zachary Silbersher as an individual.

The following Responses reflect Plaintiff’s present knowledge, information and belief and may be subject to change or modification based on Plaintiff’s further discovery, or facts or circumstances which may come to Plaintiff’s knowledge. Plaintiff specifically reserves the right to further supplement, amend or otherwise revise their Responses to these Requests in accordance with Fed. R. Civ. P. 26(e).

SPECIFIC OBJECTIONS AND RESPONSES

REQUEST NO. 1:

All documents relating to Your allegations that Defendants submitted or caused to be submitted false or fraudulent Claims for Zytiga to the Federal and/or State Government.

Response to Request No. 1:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO 2.

All documents relating to Your allegations that Defendants acted with the requisite knowledge or scienter, as set forth in Paragraphs 134 through 138 of the Second Amended Complaint.

Response to Request No. 2:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO 3.

All documents relating to Your allegations, including but not limited to those in Paragraph 142 of the Second Amended Complaint, that Defendants knowingly (a) submitted false records

and/or (b) made false statements to the Federal and/or State Government in connection with Claims for Zytiga, including such false records or statements.

Response to Request No. 3:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 4

All documents relating to allegations in the Second Amended Complaint that (a) Defendants' representations and/or omissions to the USPTO during the prosecution of the '438 Patent were false, misleading, deceptive, or otherwise fraudulent, including the allegations set forth in Paragraphs 82 through 90 of the Second Amended Complaint; and (b) Defendants had knowledge that the '438 Patent was invalid or unenforceable.

Response to Request No. 4:

Plaintiff objects to this request to the extent it mischaracterizes the allegations in the Second Amended Complaint. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST No. 5:

All documents relating to the commercial success of Zytiga, including but not limited to the reasons for Zytiga's commercial success and/or market share.

Response to Request No. 5:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 6:

All documents relating to actual or potential (a) competition, (b) market share, (c) relative price and/or cost, and (d) utilization rates between Zytiga, generic equivalents of Zytiga, and/or any pharmaceutical product approved for one or more of the same indications as Zytiga.

Response to Request No. 6:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 7:

All documents relating to any comparisons between and among Zytiga and any other pharmaceutical product approved for one or more of the same indications as Zytiga, including but not limited to actual, projected, or claimed use, and benefit, harm, improvement, therapeutic equivalence, effectiveness, similarity, or difference between or among those treatments.

Response to Request No.7

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 8:

All documents relating to Your allegations in the Second Amended Complaint, including those in Paragraphs 92 through 105 of the Second Amended Complaint, that Defendants fraudulently intended to exclude generic competitors from the market.

Response to Request No. 8:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 9:

All documents regarding or relating to the effect of a generic product's entry into the market on Zytiga.

Response to Request No. 9:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 10:

All documents relating to Your allegations that the price of Zytiga was "artificially inflated."

Response to Request No. 10:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 11:

All documents relating to Your allegation that Claims for generic versions of abiraterone acetate would have replaced approximately 90% of Claims for Zytiga submitted to the Federal and/or State Government.

Response to Request No. 11:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 12:

All documents showing or tending to show whether the Federal and/or State Government considers patent status as part of its contracting, reimbursement, or payment procedures for pharmaceutical drugs.

Response to Request No. 12:

In addition to the General and Specific Objections, Plaintiff objects to this Request to the extent the word “considers” is ambiguous. Moreover, this request speculates about which documents purport to show what the Government “considers” about a particular issue. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 13:

All documents relating to (a) the following articles written by You on the MarkmanAdvisors.com Patent Blog: *Will MorphoSys win the Darzalex patent case against Janssen and Genmab?* and *Is J&J's Remicade® part of the “rigged” system claimed by FDA's*

Gottlieb? Pfizer's Inflectra® antitrust suit has the answer; and (b) any articles, posts, or commentary You have authored or co-authored, regardless of where posted or published, relating to whether the Federal Government does or should consider patent validity when approving an application for the sale and marketing of a pharmaceutical drug and/or regulate the use of patents in connection with the sale and marketing of a pharmaceutical drug.

Response to Request No. 13:

In addition to the General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. The request also contains faulty premises, including, without limitation, incorrect assumptions concerning the process by which the Government approves the sale and marketing of pharmaceutical products. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 14:

All documents regarding or relating to any research, investigation, or analysis addressing or evaluating (a) the effect that obtaining multiple patents on a brand name pharmaceutical product has on that product's price or (b) theories of potential liability that could arise from alleged fraudulent or inequitable conduct in a patent prosecution.

Response to Request No. 14:

In addition to the General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without

waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession obtained by or created by Plaintiff prior to Plaintiff contacting counsel to investigate and file this *qui tam* action that are located after a reasonably diligent search.

REQUEST NO. 15:

All documents and communications relating to any investigation, including but not limited to the initiation of any such investigation, that You or anyone on Your behalf conducted regarding Defendants' application for, or prosecution or enforcement of, the '438 Patent; the granting of the '438 Patent or the listing of the '438 Patent in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the "Orange Book"; any Claims for payment or reimbursement for Zytiga; and/or any other facts related to the subject matter of this Litigation.

Response to Request No. 15:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession obtained by or created by Plaintiff prior to Plaintiff contacting counsel to investigate and file this *qui tam* action that are located after a reasonably diligent search.

REQUEST NO. 16:

All documents relating to Zytiga, the '438 Patent, Defendants, or the subject matter of this Litigation.

Response to Request No. 16:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 17:

All documents and communications exchanged between You and any person, including but not limited to the Federal and/or State Government, relating to Zytiga, the '438 Patent, Defendants, or this Litigation.

Response to Request No. 17:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search, except that Plaintiff will not produce any communications with the Federal or any State Government in connection with the filing of this *qui tam* or any other *qui tam* under federal or state laws, and Plaintiff will not produce any documents sent to or received from counsel retained in connection with investigating and filing this *qui tam* action or any other *qui tam* under federal or state laws.

REQUEST NO. 18:

All documents relating to Your submissions to and/or meetings with the Federal and/or State Government, including but not limited to the submissions to or meetings with the Federal

Government and any other State Government on November 2, 2018 and June 5, 2019, as set forth in Paragraph 17 of the Second Amended Complaint, or on any other date.

Response to Request No. 18:

In addition to the General and Specific Objections, Plaintiff objects that all such requested documents are privileged and protected by the attorney work product doctrine.

REQUEST NO. 19:

All documents used, referenced, or relied upon in drafting or otherwise underlying any iteration of Your Complaint in this Litigation.

Response to Request No. 19

In addition to the General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence in that the Court's ruling on the public disclosure issue is law of the case. Plaintiff will not produce, for example, the legal and other research conducted by counsel in preparing and filing the Complaint in this Litigation. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 20:

All documents, including but not limited to research summaries, analyses, memoranda, investigation material, or reports, that You contend make You an “original source” within the meaning of the False Claims Act as set forth in Paragraph 17 of the Second Amended Complaint.

Response to Request No. 20:

In addition to the General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence in that the Court’s ruling on the public disclosure issue is law of the case. Plaintiff also objects to this Request because it contains a faulty premise concerning what qualifies a relator as an “original source” within the meaning of the False Claims Act.

REQUEST NO. 21: All documents that You provided to the Federal and/or State Government relating to Zytiga, the ’438 Patent, or this Litigation and which You claim the Federal and/or State Government did not previously have or could not have acquired through publicly available resources.

Response to Request No. 21:

In addition to the General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence in that the Court’s ruling on the public disclosure issue is law of the case. Plaintiff also objects to producing any communications with the Federal or any State Government in connection with the filing of this *qui tam* or any other *qui tam* under federal or state laws, and Plaintiff will not produce any documents

sent to or received from counsel retained in connection with investigating and filing this *qui tam* action or any other *qui tam* under federal or state laws.

REQUEST NO. 22:

All documents relating to the pricing and listing of Zytiga on the Federal Supply Schedule.

Response to Request No. 22:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 23:

All documents relating to the listing of the '438 Patent in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the "Orange Book."

Response to Request No. 23:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 24:

Documents sufficient to show each client that You and/or Markman Advisors have represented in a consultant role since 2015.

Response to Request No. 24:

In addition to the foregoing General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Plaintiff further objects

to producing any documents within its possession, custody or control relating to any of his clients unrelated to Zytiga® or this litigation. As to any documents not specifically excluded, Plaintiff states that there are no responsive documents.

REQUEST NO. 25:

Documents sufficient to show each client that You and/or Kroub, Silbersher & Kolmykov PLLC have represented as legal counsel since 2015.

Response to Request No. 25:

In addition to the foregoing General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Plaintiff further objects to producing any documents within its possession, custody or control relating to any of his clients unrelated to Zytiga® or this litigation. As to any documents not specifically excluded, Plaintiff states that there are no responsive documents.

REQUEST NO. 26:

All documents provided to any of Your or Markman Advisors' consulting clients or potential consulting clients relating to (a) fraud or inequitable conduct in a patent prosecution; (b) the effect and/or propriety of obtaining multiple patents on a single brand name drug; (c) the use or application of a "commercial success" argument to procure a patent; and/or (d) theories of liability for conduct before the USPTO.

Response to Request No. 26:

In addition to the foregoing General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Plaintiff further objects

to producing any documents within its possession, custody or control relating to any of his clients unrelated to Zytiga® or this litigation. As to any documents not specifically excluded, Plaintiff states that there are no responsive documents.

REQUEST NO. 27:

All communications with Flat Line Capital LLC, or any person acting on Flat Line Capital LLC's behalf, relating to the claims and allegations in *United States ex rel. Silbersher v. Valeant Pharm. Int'l Inc., et al.*, Civil Case No. 3:18-cv-01496-JD (N.D. Cal.), including the origin of information resulting in those claims and allegations, and any documents and communications with current and/or former clients relating to the use of information for litigation pursuant to the False Claims Act, 31 U.S.C. §§ 3729 – 3733, or Federal antitrust laws, and documents concerning those communications.

Response to Request No. 27:

In addition to the foregoing General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Plaintiff further objects to producing any documents within its possession, custody or control relating to any of his clients unrelated to Zytiga® or this litigation. As to any documents not specifically excluded, Plaintiff states that there are no responsive documents.

REQUEST NO. 28:

Documents sufficient to show matters before Federal courts and/or the USPTO, including the Patent Trial and Appeal Board, in which You have appeared on behalf of, or acted as a

consultant for, (a) parties asserting a patent infringement claim and/or (b) patent owners defending an *inter partes* review challenge.

Response to Request No. 28:

In addition to the foregoing General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Plaintiff further objects to producing any documents concerning Plaintiff's documents relating to any client or potential client of any firm for which he is employed other than with respect to Zytiga® or this litigation. As to any documents not specifically excluded, Plaintiff states that there are no responsive documents.

REQUEST NO. 29:

All documents relating to any case, other than this Litigation, that You have either filed as a Relator, plan to file as a Relator, appear as legal counsel, or plan to appear as legal counsel, that includes an allegation that a false Claim has been submitted to the Federal and/or State Government.

Response to Request No. 29:

In addition to the foregoing General and Specific Objections, Plaintiff objects to this Request as overbroad and neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence. Plaintiff further objects to producing any documents concerning Plaintiff's documents relating to any *qui tam* or potential case that does not involve Zytiga® or this litigation, or which may be subject to any seal requirements or orders. As to any documents not specifically excluded, Plaintiff states that there are no responsive documents.

REQUEST NO. 30:

All documents relating to any funding you have solicited, considered, and/or received for this Litigation.

Response to Request No. 30:

In addition to the foregoing General and Specific Objections, Plaintiff objects to producing any documents beyond the scope required to be produced under Local Civil Rule 7.1.1. As to any documents or information that is subject to disclosure under Local Civil Rule 7.1.1, Plaintiff states that there are no responsive documents.

REQUEST NO. 31:

Documents relating to Your alleged damages in this Litigation, including but not limited to calculation of damages and penalties sought by Your Litigation.

Response to Request No. 31:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 32:

All documents identified in Your Rule 26 Initial Disclosures served on Defendants and any supplements to those Initial Disclosures You may serve in the future.

Response to Request No. 32:

Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce non-privileged, responsive documents in his possession that are located after a reasonably diligent search.

REQUEST NO. 33:

All documents You have received, or will receive, from non-parties in connection with this Litigation, including all documents You have received or will receive pursuant to any third-party subpoena duces tecum.

Response to Request No. 33:

Plaintiff objects to this request as overbroad vague and ambiguous. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff will produce nonprivileged, responsive documents that he has or will receive pursuant to any third-party subpoena duces tecum.

Dated: April 25, 2022

**LITE DEPALMA GREENBERG
& AFANADOR, LLC**

/s/ Bruce D. Greenberg

Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
bgreenberg@litedepalma.com

HERRERA KENNEDY LLP

Nicomedes Sy Herrera (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com

GOLDSTEIN & RUSSELL, P.C.

Tejinder Singh (*pro hac vice*)
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636
TSingh@goldsteinrussell.com

*Attorneys for Plaintiff-Relator
Zachary Silbersher*

EXHIBIT D

SF BAY AREA
NEWPORT BEACH

WWW.HERRERAKENNEDY.COM



NICOMEDES SY HERRERA
1300 CLAY STREET SUITE 600
OAKLAND, CA 94612
NHERRERA@HERRERAKENNEDY.COM

October 10, 2022

VIA ELECTRONIC MAIL

SIDLEY AUSTIN LLP
Gordon G. Todd
Robert D. Keeling
Kimberly Leaman
1501 K Street, N.W.
Washington, D.C. 20005

SILLS CUMMIS & GROSS P.C.
Jeffrey J. Greenbaum
Gregory E. Reid
One Riverfront Plaza
Newark, NJ 07102

Re: Pending Discovery Matters
United States ex rel. Silbersher v. Janssen Biotech, et al.,
Civil Action No. 19-12107 (KM-ESK) (D.N.J.)

Dear Counsel:

We write to respond to Robert Keeling's September 7, 2022 letter concerning Relator's objections to Defendants' first amended Requests for Production ("RFPs").

I. Relator's Privilege Objections

Relator first contacted counsel concerning these cases on January 10, 2016. As we set forth in our responses to defendants' request numbers 14 and 15, relator objects and will not produce any correspondence concerning this litigation with his attorneys or potential attorneys from and after that date.

Relator first contacted the Government and the Plaintiff States when counsel, on Relator's behalf, made pre-filing disclosures to the government entities on June 20, 2017. Relator's counsel then served post-filing disclosures to the government entities on December 22, 2017. Since that time, counsel has corresponded occasionally with the responsible government entities on behalf of Relator. Relator has not personally contacted any government entity concerning this matter directly. All correspondence through counsel are privileged and not a proper area for discovery.

II. Relator's Objections Based on Law-of-the-Case

Relator has not withheld any documents for RFPs 19-21 on the basis of law of the case or relevance. We note that if Relator viewed or consulted sources online without downloading such documents, those documents are not within his possession, custody or control.

III. Relator's Objections on Responsiveness and Breadth

Relator disagrees with defendants' framing of the relevant issues in this case, or the applicability of Relator's consulting or legal work for other pharmaceutical patents or drugs other than those at issue in this case. Nevertheless, we answer below your questions concerning whether any documents have been withheld on the basis of relevance for the listed RFPs.

A. *Requests Concerning Relator's Research, Views, and Opinions*

- RFP 13.** The referenced articles—neither of which concern Zytiga or any of the patents at issue in this matter—are publicly available. Relator has produced documents relating to his research for those articles that are within his possession, custody or control. Relator has also produced all prior drafts of those articles. Apart from that, this request is overbroad and lacks reasonable denotation to the extent that it seeks documents or information, beyond the scope of the drug at issue in this case, that may be “related” to whether the government “does or should consider patent validity” in connection with drug approvals or “does or should . . . regulate the use of patents” in connection with drug approvals. With respect to any articles, posts or commentary that may potentially be responsive to those topics, they are publicly-available, and it is unreasonably burdensome for Relator to produce publicly-available information in response to an overly broad request. The request also seeks irrelevant information. This is a *qui tam* action, and the ultimate claim belongs to the Government, not to Relator. Defendants' liability will be assessed against the appropriate and applicable legal standards as determined by the court; not against Relator's prior or earlier statements regarding topics sought within this request, to the extent those prior statements exist.
- RFP 14.** We disagree that this request seeks information that is “directly relevant to this case.” For the reasons stated above in connection with RFP 13, Defendants' liability in this action will be assessed against the appropriate and applicable legal standards as determined by the Court; not against Relator's prior or earlier statements regarding topics sought within this request, to the extent

those prior statements exist. Relator's production is therefore limited based on relevance consistent with the same factors described above.

- **RFPs 24 & 26.** These requests seek irrelevant and overly broad information for the same reasons articulated above in connection with RFPs 13 and 14. Neither Relator nor Markman have had any consulting clients with respect to Zytiga or any of the patents at issue in this litigation. Relator has produced all documents within his possession, custody or control concerning any correspondence with a client or potential client that mentions Zytiga or any patents at issue in this action. The request is otherwise burdensome and potentially harassing to the extent it seeks lists of clients or potential clients that are unrelated to the drug at issue in this case.
- **RFPs 25 & 28.** Neither Relator nor Kroub have had any legal clients with respect to Zytiga or any of the patents at issue in this litigation. In addition to his objections set forth above, Relator also believes that any discovery into his legal clients that have no connection whatsoever with Zytiga or this case are improper on the basis of privilege. The request is also potentially harassing to the extent that Defendants suggest that they intend to seek further discovery either from or regarding those clients ("will allow Defendants to conduct further diligence on those representations"). To the extent none of Relator's or Kroub's prior or existing client relationships are related to Zytiga, it would be potentially harassing for Defendants to subpoena or contact those clients to seek information regarding potentially privileged and confidential communications.

B. Other Requests

- **RFP 12.** Relator has searched for, and produced, documents concerning his research into Federal and/or State Government contracting, reimbursement, or payment procedures that were obtained prior to contacting counsel. After that time, all such research was performed by or under the direction of counsel in connection with filing and prosecuting this action. We note that if Relator viewed or consulted sources online without downloading such documents, those documents are not within his possession, custody or control.
- **RFP 27.** Relator stands by his objections. This request seeks irrelevant information. Defendants' affirmative defense of unclean hands, as pled, included no facts or allegations to support the defense. Courts have also held that unclean hands is not a defense to liability in a *qui tam* action. *See e.g., U.S. v. Ctr. for Diag. Imag., Inc.*, 2011 U.S. Dist. LEXIS 145165, at 5 (W.D. Wash. Dec. 16, 2011) ("The Court notes that the Ninth

Circuit has already concluded that a qui tam defendant may not defend an FCA action by asserting that a qui tam plaintiff has unclean hands."); *U.S. ex. re. Donald Gale v. Omnicare, Inc.*, Case No. 10-127, at *19-20 (N.D. Ohio, Jul. 23, 2013. For both these reasons, Defendants' unclean hands defense is subject to being stricken. The request is also irrelevant to the extent it seeks information regarding a wholly separate matter that is unrelated to this action.

- **RFP 29.** Relator stands by his objections to this request for the reasons set forth above. Relator also objects to any attempted discovery or inquiry into any possible sealed cases.
- **RFP 30.** We do not agree that any discovery beyond what is required to be disclosed under Local Civil Rule 7.1.1 is reasonably likely to lead to admissible evidence. Nor do we agree, and you have not explained why, Relator's possible solicitation or consideration of litigation funding would be relevant.
- **RFP 33.** We confirm that Relator has not limited his responses or his document production to third-party subpoenas. We do not include in Relator's responses documents that any of Relator's counsel or potential counsel have received from third parties in connection with their diligence or prosecution of this action (other than documents received through a subpoena). For example, if Relator's counsel received documents from its experts, those documents will not be produced.

Please let us know if you would like to discuss any of these matters further.

Very truly yours,

/s/ Nicomedes Sy Herrera

Nicomedes Sy Herrera

cc:

Bruce D. Greenberg
LITE DEPALMA GREENBERG
& AFANADOR, LLC

Tejinder Singh
SPARACINO PLLC

EXHIBIT E

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA; STATES OF
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, VERMONT, AND WASHINGTON;
THE COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA; AND
THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH &
DEVELOPMENT, LLC, JOHNSON &
JOHNSON, and BTG INTERNATIONAL
LIMITED,

Defendants.

Civil Action No.: 19-12107 (KM)(JBC)

**PLAINTIFF-RELATOR ANSWERS TO TO DEFENDANTS' FIRST SET OF
INTERROGATORIES**

**LITE DEPALMA GREENBERG
& AFANADOR, LLC**

Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

Attorneys for Plaintiff-Relator Zachary Silbersher
[Additional Counsel on Signature Page]

GENERAL OBJECTIONS

Pursuant to Fed. R. Civ. P. 26 and 33, Plaintiff-Relator Zachary Silbersher (“Plaintiff”) hereby object to defendants’ First Set of Interrogatories (collectively, “Interrogatories”) as follows:

A. Each of Plaintiff’s responses, in addition to any specifically stated objections, is subject to and incorporates the following General Objections. The assertion of the same, similar, or additional objections, or a partial response to an individual Request does not waive any of Plaintiff’s General Objections.

B. Plaintiff objects to Defendants’ instructions to the extent they conflict with the Federal Rules of Civil Procedure or seek to add obligations not found in those rules.

C. Plaintiff objects to the definition of “YOU” or “YOUR” to the extent they refer to Plaintiff’s attorneys and persons employed or retained by non-parties to this action. In the answers below, we limit “YOU” and “YOUR” to Zachary Silbersher as an individual.

D. Plaintiff objects to these Interrogatories to the extent that they seek information that is neither relevant to the claims or defenses of any party to this litigation, nor reasonably calculated to lead to the discovery of admissible evidence.

E. Plaintiff objects to these Requests to the extent that they seek information protected from disclosure by the attorney-client privilege, the attorney work product doctrine, or any other applicable privilege, protection, or immunity. No information subject to such privilege, protection, or immunity will be provided. Plaintiff construes all of Defendants’ requests to exclude privileged information.

F. In response to these Interrogatories, Plaintiff does not concede that any of the answers or information contained herein is relevant or admissible. Plaintiff reserves the right to

object, on the grounds of competency, privilege, relevance, materiality, or otherwise, to the use of this information for any purpose, in whole or in part, in this action or in any other action.

G. Plaintiff objects to these Interrogatories to the extent that they call for legal conclusions or otherwise attempt to re-cast legal issues as factual matters.

H. Plaintiff objects to any Interrogatories to the extent the request is vague or ambiguous.

I. Unless otherwise stated, Plaintiff will not provide any information encompassed by the foregoing objections.

J. The following Answers reflect Plaintiff's present knowledge, information and belief and may be subject to change or modification based on Plaintiff's further discovery, or facts or circumstances which may come to Plaintiff's knowledge. Plaintiff specifically reserves the right to further supplement, amend or otherwise revise his Answers to these Interrogatories in accordance with Fed. R. Civ. P. 26(e).

SPECIFIC OBJECTIONS AND RESPONSES

INTERROGATORY NO. 1:

Identify each instance in which You or Your counsel were in contact with the Federal Government and/or any State Government in connection with the subject matter of this Litigation, including specific dates, the participants included in the Communication, and the manner of Communication.

Answer to Request No. 1:

Through counsel, Plaintiff first contacted the Federal Government and certain State Governments on June 20, 2017, when Plaintiff made his pre-filing disclosures. In particular, Plaintiff contacted Attorney General Jefferson Beauregard Sessions III and United States Attorney Brian Stretch, as well as the attorneys general and relevant authorities for the Plaintiff States. Plaintiff objects to this interrogatory to the extent it requests information concerning subsequent

contacts with the Federal Government and the Plaintiff States concerning this lawsuit, because those communications are protected by attorney-client privilege and attorney work product doctrine.

INTERROGATORY NO 2.

Identify the dates on which You first retained counsel in connection with this action.

Answer to Interrogatory No. 2:

Plaintiff objects to this interrogatory to the extent it requests information protected by attorney-client privilege and attorney work product doctrine. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff first contacted counsel about cases related to patent fraud on January 10, 2016, and first contacted Nicomedes Sy Herrera to retain him to pursue such cases in September 2016.

INTERROGATORY NO 3.

Describe with particularity the basis for Your statement that “Relator provided independently-obtained information that materially adds to any public disclosure of any aspect of the fraud alleged herein.” Compl. ¶ 17.

Answer to Interrogatory No. 3:

Plaintiff answers that the allegations set forth within the Second Amended Complaint disclose information collected from numerous disparate sources and detail allegations of fraud that have not, to Plaintiff’s knowledge, been previously documented or disclosed elsewhere in the form or substantiated in the manner as set forth within the Second Amended Complaint. The results of Plaintiff’s investigation, based upon his unique expertise regarding the intersection of both patent law and the regulation of generic pharmaceutical drugs, include information that is independent of that which Defendants have alleged was disclosed in purported public fora enumerated within 31

U.S.C. § 3730(e)(4)(A)(i)-(iii). Without limiting the foregoing, the facts and analysis that Plaintiff provides in the following paragraphs of the Second Amended Complaint are independent of any disclosures that may be contained within the channels enumerated in 31 U.S.C. § 3730(e)(4)(A)(i)-(iii): Paragraphs 8, 9, 17, 43, 44-45, 53, 58, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 75-83, 84(a)-(f), 85, 86, 87(a)-(i), 92, 93, 94, 96, 97, 99, 100, 105, 107, 112, 113, 114, 115, 117, 124, and 125.

INTERROGATORY NO. 4

Describe with particularity the “independent investigation” that caused Relator to believe “Defendants withheld material information from the Patent Office that the claimed commercial success of Zytiga lacked any nexus to the claimed invention in the ’438 Patent,” Identify the “material information,” and explain why the information would have been material to any determination(s) made by the Patent Office. Complt. ¶¶ 16-17, 120.

Answer to Interrogatory No. 4:

Plaintiff objects to this interrogatory to the extent the requested description of an “independent investigation” is vague and ambiguous. Plaintiff further objects to this request as vague and ambiguous, overly broad and unduly burdensome to the extent it seeks information that is facially redundant with that requested in Interrogatory No. 3. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff respectfully refers to his answer to Interrogatory No. 3 as well as the Second Amended Complaint, including, without limitation, Paragraphs 63 to 91, as responsive to this Interrogatory.

INTERROGATORY No. 5:

Describe with particularity Your understanding of the invention claimed by the ’438 Patent, including Identifying the feature(s) of the invention that were material to any determination made

by the Patent Office, and explain why You contend that such feature(s) lack nexus to the Commercial Success of the invention.

Answer to Interrogatory No. 5:

Plaintiff objects to this Interrogatory as vague and ambiguous to the extent the phrase “explain why You contend that such feature(s) lack nexus to the Commercial Success of the invention” relies upon a definition of “Commercial Success” that encompasses potentially inconsistent positions, contentions and arguments made by certain parties and third-parties. Subject to and without waiving the foregoing General and Specific Objections, Plaintiff refers to the language of the claims of the ’438 Patent for the invention of the ’438 Patent. Plaintiff also refers to the Second Amended Complaint, including, without limitation, Paragraphs 63 to 91, as responsive to this Interrogatory. In addition, the Examiner for the ’340 Application leading to the ’438 Patent asserted on September 11, 2012 that, “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and aiberaterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer.” To surmount the Examiner’s finding of obviousness, on June 4, 2013, Defendants purported to demonstrate to the Patent Office that “the present invention has displayed commercial success” based upon information related to the purported commercial success of Zytiga. Yet, the factual allegations described in Paragraphs 84(a)-(f) and 87(a)-(i) of the Second Amended Complaint, individually and collectively, demonstrate that any purported commercial success of Zytiga, as of June 4, 2013, was unrelated to the “presently claimed invention” as of that date.

INTERROGATORY NO. 6:

Provide all factual and legal bases and/or arguments refuting or supporting the validity of the claims of the '438 Patent, including a detailed explanation of why You contend the '438 Patent is invalid under 35 U.S.C. § 103 and why You contend "Defendants knew the fraudulent '438 Patent eventually would have been invalidated," Cmpl't. ¶ 9.

Answer to Interrogatory No. 6:

Plaintiff refers to the factual and legal bases determining claims of the '438 Patent are invalid set forth within the Final Written Decisions of the *inter partes* review proceedings that challenged the validity of the '438 Patent; in the Court's decision in *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp. 3d 352 (D.N.J. 2018); and in the Federal Circuit's decision in *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Circ. 2019). Plaintiff also refers his responses to Interrogatory Nos. 3-5 as well as to the Second Amended Complaint, including, without limitation, Paragraphs 63 to 91, as responsive to this Interrogatory. Defendants knew the fraudulent '438 Patent eventually would have been invalidated because, *inter alia*, on June 4, 2013, Defendants submitted information to the Patent Office related to the purported commercial success of the inventions recited in the pending claims of the '438 patent even though Defendants were aware that information would have been equally relevant to the purported commercial success of the invention claimed in the '213 patent. Plaintiff further answers that the '438 patent is a continuation of U.S. Patent Application No. 11/844,440 ("the '440 application"), which was filed on August 24, 2007. The '440 application recited pending claims that are in many cases identical to the claims that issued in the '438 patent as well as the claims from the '438 patent that were asserted in litigation against the Zytiga generics. After numerous rejections by the Examiner, the '440 application was eventually abandoned.

INTERROGATORY NO. 7:

Describe with particularity the basis for Your claim that any attorney employed by or acting on behalf of J&J breached their duty of candor to the U.S. Patent Office and Identify each and every fact that You contend should have been but was not disclosed to the Patent Office in connection with the '340 Application.

Answer to Interrogatory No.7

Plaintiff refers to the Second Amended Complaint, including, without limitation, Paragraphs 63 to 91, as responsive to this Interrogatory. During prosecution of the '438 patent, the attorneys and non-attorney individuals who acted on behalf of Defendants, including J&J, and owed a duty of candor and good faith in connection with this patent application, breached that duty by failing to disclose to the Patent Office, at least, the factual allegations described in Paragraphs 84(a)-(f) and 87(a)-(i) of the Second Amended Complaint, and further breached that duty by recklessly or intentionally failing adequately to investigate the reasons for Zytiga's purported commercial success before making representations to the Patent Office regarding it. Plaintiff further answers that the '438 patent is a continuation of U.S. Patent Application No. 11/844,440 ("the '440 application"), which was filed on August 24, 2007. The '440 application recited pending claims that are in many cases identical to the claims that issued in the '438 patent as well as the claims from the '438 patent that were asserted in litigation against the Zytiga generics. After numerous rejections by the Examiner, the '440 application was eventually abandoned.

INTERROGATORY NO. 8:

State whether You reported Andrea Kamage, Timothy Tracy, or any other attorney employed by or acting on behalf of J&J to the Patent Office for committing a fraud on, and/or breaching their

duty of candor to, the Patent Office. If so, Identify the date of that report, and describe all steps taken by You to investigate such report.

Answer to Interrogatory No. 8:

Plaintiffs object to this interrogatory because it seeks information that is irrelevant to the claims and defenses in this case and not likely to lead to the discovery of admissible evidence. Plaintiff further objects to this interrogatory to the extent it mischaracterizes Plaintiff's allegations. Plaintiff further objects to this Interrogatory to the extent it presumes there is a mechanism at the Patent Office for receiving the type of reports contemplated by the Interrogatory, whereas it is the policy of the Patent Office not to field or investigate such types of reports, especially after issuance of the Notice of Allowance, but rather leave those types of determinations to the courts. (*See e.g.*, MPEP § 2010). Subject to, and without waiving, any of the General and specific objections, Plaintiff states that he has not reported Andrea Kamage, Timothy Tracy, or any other attorney employed by or acting on behalf of J&J to the Patent Office for committing a fraud on, and/or breaching their duty of candor to, the Patent Office.

INTERROGATORY NO. 9:

Identify each representation in which You served as legal counsel and/or consultant that:

- (1) involved Commercial Success as a secondary consideration in support of patentability; and/or
- (2) raised a claim of a breach of the duty of candor and/or inequitable conduct.

Answer to Interrogatory No. 9:

Plaintiffs object to this interrogatory because it seeks information that is irrelevant to the claims and defenses in this case and not likely to lead to the discovery of admissible evidence.

INTERROGATORY NO. 10:

Describe with particularity the false or misleading nature of each claim for which You contend Defendants are liable in this Litigation.

Answer to Interrogatory No. 10:

Plaintiff objects to this Interrogatory as vague and ambiguous to the extent that Plaintiff has not contended that his claims, as set forth in paragraphs 139 to 496 of the Second Amended Complaint, possess a false or misleading nature. To the extent that Plaintiff understands the information sought by this Interrogatory, Plaintiff refers to the Second Amended Complaint, including, without limitation, Paragraphs 63 to 91, as well as Plaintiff's responses to Interrogatory Nos. 4, 5 and 7, as responsive. Moreover, subject to and without waiving the foregoing General and specific objections, Plaintiff further states that each and every claim for payment or reimbursement for Zytiga is false within the meaning of the False Claims Act, 31 U.S.C. §§ 3729-33, because (i) Defendants' representations to PTO in order to obtain the '438 Patent were false or misleading; (ii) Defendants' misrepresentations to the Patent Office tainted subsequent claims for payment for Zytiga because it allowed Defendants to unlawfully exclude generic competitors, which would have taken substantial market share from Defendants while substantially lowering the price the Government and the Plaintiff States would have otherwise paid; and (iii) Defendants' misrepresentations to government agencies wrongfully portrayed Zytiga's price as "fair and reasonable" when it was not. Therefore, each and every claim for payment or reimbursement for Zytiga during the relevant time period was false within the meaning of the False Claims Act because the price requested in each of the claims were unlawfully inflated, and also because Defendants would not have been entitled to receive payment at all for all such claims.

INTERROGATORY NO. 11:

Describe with particularity each and every false certification, express or implied, that You contend was submitted to a Federal and/or State Government.

Answer to Interrogatory No. 11:

Plaintiff refers to the Second Amended Complaint, including, without limitation, Paragraphs 106 to 138, as responsive to this Interrogatory. Moreover, subject to and without waiving the General Objections, Plaintiff further states that Defendants impliedly certificated, falsely, that the prices it was selling Zytiga to the Government, the prices Defendants listed in the Federal Supply Schedule, and the prices for which reimbursement were sought were “fair and reasonable,” *i.e.*, not inflated through the unlawful exclusion of competitors. Without limiting the foregoing, Plaintiff further answers that Defendants falsely implied that Zytiga’s prices were fair and reasonable as a condition for participation in various Government programs, including, without limitation, the GSA’s Federal Supply Schedule, the HHS’s Medicaid Drug Rebate Program, and the HHS’s Section 340B Drug Pricing Program, all of which Defendant used to sell Zytiga directly to government agencies or to receive reimbursement through Medicaid.

INTERROGATORY NO. 12:

State the amount of damage You are seeking in this Litigation including a detailed calculation for each category thereof.

Answer to Interrogatory No. 12:

Plaintiff states that he is still seeking discovery necessary to calculate damages from direct purchases of Zytiga from the Government. With respect to Medicare and Medicaid payments, Plaintiff states that the precise amount of damages will be calculated by Plaintiff’s experts. This interrogatory therefore improperly seeks information better obtained through expert discovery.

Subject to the foregoing objections, based on data of drug utilization provided by the Centers for Medicare and Medicaid Services, the Government paid or reimbursed at least \$2.1 billion more than it should have for Medicare and Medicaid during the time that generic manufacturers were unlawfully excluded from the market because of the fraudulent '438 Patent. These payments resulted from the submission of over 500,000 separate false claims. With trebling and statutory penalties, Plaintiff will therefore seek at least \$18 billion in damages on behalf of the Government and the Plaintiff States related to Medicare and Medicaid alone.

INTERROGATORY NO. 13:

Identify each instance in which (i) You, or anyone acting on Your behalf; (ii) Your spouse, Eleise Jones, or anyone acting on her behalf; (iii) members of Your immediate family (i.e., grandparents, parents, siblings, or children) and anyone acting on their behalf; (iv) Markman Advisors (including any partners thereof); or (v) Kroub, Silbersher & Kolmykov PLLC (including any partners thereof) traded, or caused to be traded, Securities in Johnson & Johnson since January 1, 2015.

Answer to Interrogatory No. 13:

Plaintiffs object to this Interrogatory because it seeks information that is irrelevant to the claims and defenses in this case and not likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing General and specific objections, Plaintiff answers that he has not since January 1, 2015 directly traded or caused to be traded any Securities of Johnson & Johnson (except as such Securities may have been included in mutual funds or portfolios managed by investment professionals as to which Plaintiff made no recommendations for specific Securities to be purchased or sold).

INTERROGATORY NO. 14:

Identify each instance in which You, Markman Advisors (including any partners thereof), or Kroub, Silbersher & Kolmykov PLLC (including any partners thereof) provided consulting advice relating to the trading in Securities in Johnson & Johnson since January 1, 2015, including the substance of the advice rendered.

Answer to Interrogatory No. 14:

Plaintiffs object to this interrogatory because it seeks information that is irrelevant to the claims and defenses in this case and not likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing General and specific objections, Plaintiff answers that he has not provided any consulting advice since January 1, 2015 relating to the buying or selling in Securities in Johnson & Johnson.

Dated: December 5, 2022

HERRERA KENNEDY LLP

/s/ Nicomedes Sy Herrera

Nicomedes Sy Herrera (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com

**LITE DEPALMA GREENBERG
& AFANADOR, LLC**

Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
bgreenberg@litedepalma.com

SPARACINO PLLC

Tejinder Singh (*pro hac vice*)
1920 L Street, NW, Suite 835
Washington, D.C. 20036
Telephone: (202) 629-3530
TSingh@sparacinopllc.com

***Attorneys for Plaintiff-Relator
Zachary Silbersher***

EXHIBIT F

SF BAY AREA
NEWPORT BEACH

WWW.HERRERAKENNEDY.COM



NICOMEDES SY HERRERA
1300 CLAY STREET SUITE 600
OAKLAND, CA 94612
NHERRERA@HERRERAKENNEDY.COM

December 16, 2022

VIA ELECTRONIC MAIL

SIDLEY AUSTIN LLP
Gordon G. Todd
Robert D. Keeling
Kimberly Leaman
1501 K Street, N.W.
Washington, D.C. 20005

SILLS CUMMIS & GROSS P.C.
Jeffrey J. Greenbaum
Gregory E. Reid
One Riverfront Plaza
Newark, NJ 07102

Re: Pending Discovery Matters
United States ex rel. Silbersher v. Janssen Biotech, et al.,
Civil Action No. 19-12107 (KM-ESK) (D.N.J.)

Dear Counsel:

We write to follow-up on the parties' meet and confer on December 9, 2022 concerning the issues raised in defendants' November 17, 2022 letters.

1. During our meet and confer, you raised questions concerning the metadata fields for two of Relator's emails produced with Bates number RELATOR_002392 and 002394. We did not manually populate any of the metadata fields. The metadata fields for these emails show the Relator as the author because a PDF of the email was generated for production. We will produce the natives of these two emails, including the attachment for 002392.

2. With respect to your question concerning privilege, Relator first contacted Mr. Herrera, the undersigned, to retain him to pursue these cases in September 2016, and retained him soon thereafter, even if a formal agreement was signed later. Even prior to a formal, signed retainer agreement, all communications from and after 2016 are privileged.

3. Relator has provided all of his responsive documents. Markman Advisors and his law firm have not acted on Relator's behalf with respect to this case.

4. With respect to RPD No. 13, you asked for a list of Relator's articles and blog posts. We will produce documents sufficient to show a list of Relator's articles and blog posts since 2014.

5. You asked about a list of unpublished articles or blogs that Relator started but did not publish. Relator has unpublished drafts of articles he has not yet completed or abandoned prior to publication. None relate to defendants or Zytiga with the exception of draft articles about these cases that have not yet published, which were created after Relator retained counsel, and which have been shared with counsel seeking legal advice. They are therefore covered by the attorney-client privilege.

6. You asked whether Relator usually creates a separate folder for research. Relator does not typically create a separate folder for research related to each individual blog post or article that he publishes. Rather, as shown by published blog posts and articles, he does include links to certain sources he relied upon within those blog posts and articles. For the specific blog posts identified in RPD 13, Relator produced the responsive source documents within his possession, custody and control.

7. With respect to defendants' RPD Nos. 14 and 26, you have asked whether Relator has produced documents provided to Relator's clients that relate to inequitable conduct or commercial success. Relator writes extensively about patent-related issues; but because none of his prior articles, blog posts or client engagements relate to Zytiga, the patents at issue in this litigation, or the application of patent doctrines to any patents at issue in this litigation, such information is irrelevant and not reasonably calculated to lead to admissible evidence.

8. With respect to RPD No. 24-28, you asked whether Relator is claiming privilege for Markman Advisor's client list. Relator does not claim an attorney-client privilege to such a list; but the identities of those clients are subject to confidentiality agreements and proprietary to Markman Advisors, which is not a party to this action. Moreover, this information is irrelevant and not reasonably calculated to lead to admissible evidence. Without waiving any of his objections, Relator confirms that no Markman Advisor client has ever retained Mr. Silbersher or Markman Advisors relating to Zytiga or any patent at issue in this litigation. You also asked about Relator's ownership of Markman Advisors. Relator objects to this information as irrelevant and not reasonably calculated to lead to admissible evidence. Without waiving his objections, Relator confirms that he does not own a majority of Markman Advisors.

9. With respect to RPD No. 24-28, you also asked whether Relator is claiming privilege for the client list of Kroub, Silbersher & Kolmykov PLLC (KSK). Relator does claim that the identities of KSK's clients are privileged, subject to

confidentiality obligations, and proprietary to KSK, which is not a party to this action. Moreover, this information is irrelevant and not reasonably calculated to lead to admissible evidence. Without waiving any of his objections, Relator confirms that no KSK client has ever retained Mr. Silbersher or KSK with respect to Zytiga, any patent at issue in this litigation, or defendants.

10. With respect to Interrogatory No. 4, Relator's independent investigation included review of the prosecution histories for the patents related to Zytiga; prior art and references; medical and clinical publications relating to prostate cancer treatments; certain regulatory filings related to Zytiga; litigation documents related to Hatch-Waxman litigations for Zytiga; post-grant proceeding documents related to patents related to Zytiga; information concerning the corporate entities involved in the development, marketing, and sale of Zytiga or abiraterone acetate; online publications related to Zytiga; market analysis concerning Zytiga and the potential for generic entry; and government purchases or reimbursement of Zytiga. All of Relator's independent investigation was conducted after contacting counsel, and some was directed based on counsel's advice. Relator asserts the attorney-client privilege and protection of the work product doctrine for this information.

11. With respect to Interrogatory No. 13, you asked whether Relator's wife, parents, or any adult children have traded in J&J securities since January 1, 2015. In Relator's answer to defendants' Interrogatory No. 13, he confirmed that he has not since January 1, 2015 directly traded or caused to be traded any Securities of Johnson & Johnson (except as such Securities may have been included in mutual funds or portfolios managed by investment professionals as to which Relator made no recommendations for specific Securities to be purchased or sold). Without waiving his objections, Relator also confirms that his wife has not directly done so as well. Relator is unaware of his parents' investments, but he confirms that he has never spoken or communicated with them concerning any purchase or sale of J&J securities. Finally, Relator has no adult children.

12. With respect to Interrogatory No. 14, Relator stands by his objections. Without waiving these objections, and in the interest of compromise, Relator is interpreting the phrase in Interrogatory No. 14, "consulting advice relating to the trading in Securities in Johnson & Johnson," to mean providing advice on whether to specifically buy or sell Securities in Johnson & Johnson, and Relator reiterates that he has not done that in either a personal or professional capacity within the enumerated time-period. Relator has consulted on behalf of Markman Advisors on patent issues relating to Remicade and Darzalex, but none of those consultations included any advice as to whether or not to buy or sell any Securities in Johnson & Johnson. To the extent the phrase, "consulting advice relating to the trading in Securities in Johnson & Johnson" is interpreted more

broadly to encompass the provision of objective opinions regarding pending patent litigation unrelated to any patent in this case, that is not “advice”, and it does not touch upon, relate to, or compromise Relator’s credibility.

13. With respect to the date range of defendants’ production relating to commercial success and patent fraud, the ‘438 patent is a continuation of U.S. Patent Application No. 11/844,440 (“the ‘440 application”), which was filed on August 24, 2007. Although the ‘440 application predates defendants’ acquisition of Cougar Biotechnology, defendants’ knowledge of the application and assessment of the commercial prospects for Zytiga / abiraterone acetate are relevant to the fraud alleged in the complaint. For example, the ‘440 application recited pending claims that are in many cases identical to the claims that issued in the ‘438 patent as well as the claims from the ‘438 patent that were asserted in litigation against the Zytiga generics. After numerous rejections by the Examiner, the ‘440 application was eventually abandoned. Moreover, defendants’ view of the commercial prospects for abiraterone prior to acquiring Cougar Biotechnology directly relates to defendants’ assessment of the commercial success of Zytiga as it may or may not be related to the inventions claimed in the ‘438 patent.

14. With respect to the date range of defendants’ production relating to the Orange Book, defendants’ documents assessing whether to list the relevant patents in the Orange Book as covering Zytiga may predate the first notice of issuance of the ‘438 patent. Therefore, it makes no sense to limit defendants’ production to the date of the first notice of issuance.

Please let us know if you would like to discuss any of these matters further. With respect to the issues referenced in numbers 13 and 14, *supra*, if defendants are unwilling to produce documents with the requested date ranges, please provide a time to conduct another meet and confer.

Very truly yours,

/s/ Nicomedes Sy Herrera

Nicomedes Sy Herrera

cc:

Bruce D. Greenberg
LITE DEPALMA GREENBERG
& AFANADOR, LLC

Tejinder Singh

SPARACINO PLLC